DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

VIASYS Healthcare GmbH
C/O Ms. Yvette Lloyd
Regulatory Affairs Manager
VIASYS Respiratory Care, Incorporated
22745 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K072061
Trade/Device Name: MasterScreen PFT Body
MasterScreen PFT CT
MasterScreen PFT
Regulation Number: 21 CFR 868.1760
Regulation Name: Volume Plethysmograph
Regulatory Class: II
Product Code: JEH
Dated: April 8, 2008
Received: April 11, 2008

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

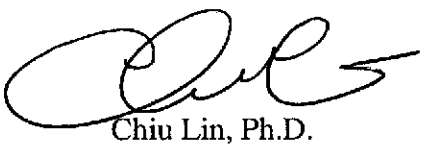
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072061

Device Name: MasterScreen PFT Body
MasterScreen PFT CT
MasterScreen PFT

Indications for Use:

The Masterscreen PFT Body is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent pulmonary function tests which include Spirometry/Flow-Volume/Resistance measurements, lung diffusion measurements and bodyplethysmography measurement. The device provides data / information and supports help for a diagnosis.

MasterScreen PFT CT (**C**linical **T**rial version) includes Spirometry/Flow-Volume/Resistance measurements and lung diffusion measurements with individual access rights defined for different user roles (e.g. Investigator, doctor, study nurse, trainer and service personnel).

MasterScreen PFT includes Spirometry/Flow-Volume/Resistance and lung diffusion measurements.

Measurements will be performed under the direction of a physician in the clinic, doctor's office or hospital. It can be utilized for patients from 4 years on and older as long as they can cooperate in the performance.
The MS-PFT Body is powered from 100-240V / 50-60Hz wall outlets. No energy is transferred to the patient.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072061